ENGLISH

BiliChek®

Non-Invasive Bilirubin Analyzer

Children's Medical Ventures

RESPIRONICS

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NOTE: Due to continual product innovation, specifications in this manual are subject to change.
For questions, please contact Respironics or your local dealer.

Printed in USA US Patents 5,353,790 5,792,049 5,860,421 5,924,981, 6,002,482, 6,226,541, 6,192,734, 6,045,502 and Patents Pending

ENGLISH

PREFACE

About This Manual

This User Instruction Manual has been prepared by Respironics, Inc. for both first-time and experienced users of the Bili*Chek*® System. This manual provides basic instructions for use and troubleshooting procedures. To ensure safe operation of this product the user should read the entire instruction manual before operating the device. Save this manual for future reference.

ENGLISH

CE NOTICE

Marking by the CE indicates compliance of this Bili*Chek* System, manufactured by Respironics, Inc. to the Medical Device Directive 93/42/EEC of 14 June 1993.

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1.0 WARRANTY AND RETURN POLICY INFORMATION

Respironics, Inc. warrants the Bili*Chek*® ("unit") to be free from defects in materials and workmanship for a period of one (1) year from the date of shipment to the user or 18 months from the date of shipment by Respironics, Inc., whichever comes first. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace, at its option, the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship. To exercise your rights under this warranty, contact your local, authorized Respironics, Inc. dealer or Respironics.

2.0 NOTATIONAL DESCRIPTIONS

Throughout this manual, there are blocks of text in bold or italic type. These blocks are warnings, cautions, notes, and technique tips and they are used as follows:

WARNING: A WARNING indicates the possibility for injury to the user or operator.

CAUTION: A CAUTION indicates the possibility of damage to the device.

NOTE: A NOTE provides important general information that will help you make better use of your product.

TECHNIQUE TIP: A Technique Tip indicates important specific information that will help you make better use of your product.

2.1 SYMBOLS

- Symbol for “Attention, See Instructions For Use”

- Symbol for “Used With”

- Symbol for “Do Not Reuse”

- Symbol for “Use By”

- Symbol for “Batch Code”

- Symbol for “Recycle”

- Symbol for “Serial Number”

- Symbol for “Catalog Number”

- Denotes this system is ETL Listed and conforms to ANSI/UL STD. 2601. Certified to CAN/CSA C22.2 STD. NO. 601.1.

- Symbol for “Battery Deep Discharge and Recharge”

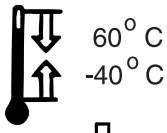
- Symbol for “Battery Charging”

- Symbol for “Rechargeable Battery Recycle Corporation”

- Symbol for “Do Not Throw in Trash”

- Symbol for “Nickel Cadmium Battery”

- Symbol for “Storage Conditions”



- Symbol for “Date of Manufacture”

- Symbol for “Indoor Use”

- Symbol for “Class B”

3.0 INTRODUCTION

Jaundice is a condition characterized by yellowing of the skin and eyes that is caused by an excess of bilirubin in the blood. Bilirubin is a normal waste product resulting from the breakdown of red blood cells and is removed from the body by the liver. Prior to birth, bilirubin in an infant is processed by the mother's liver and excreted. After birth, an infant must eliminate bilirubin without the mother's help. It may take the infant's system several days to begin eliminating bilirubin from the blood faster than it is produced. Infants who are born prematurely, who are underfed, or who belong to certain ethnic groups are at increased risk of developing jaundice. The initial screening of jaundice is the observation of yellow skin. This is a subjective determination prone to errors due to differing skin colors and gestational ages. Bilirubin levels normally peak in full-term infants 4 to 5 days after birth and may peak later in premature infants. If the infant's serum bilirubin levels continue to rise the infant is at risk for kernicterus (the deposit of bilirubin in the brain at toxic levels which can cause permanent neurologic impairment).

4.0 PURPOSE OF THE DEVICE

The Bili*Chek*® Non-Invasive Bilirubin Analyzer is a non-invasive transcutaneous bilirubinometer, which predicts total serum bilirubin levels before, during, and post phototherapy in neonates without regard to gender, gestational age, race, or bodyweight. Neonates whose Bili*Chek* test results are indicative of hyperbilirubinemia must be evaluated by their physician(s) for appropriate patient management. The Bili*Chek* provides a numerical measurement of predicted bilirubin count in mg/dL or µmol/L within a clinically beneficial range that has been correlated with total serum bilirubin concentration measured by High Pressure Liquid Chromotography (HPLC). The device is used by Health Care Professionals to assist clinicians in monitoring the status of neonates for the development of hyperbilirubinemia.

5.0 THEORY OF OPERATION

The Bili*Chek* works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths that are returned. By knowing the spectral properties of the components within the skin, one can subtract out the interfering components and determine the concentration of bilirubin.

Each photon has a characteristic wavelength. As light enters skin tissue it can collide with the structural components such as collagen fibers. When a collision occurs, the photon loses energy and the direction of travel is changed. This is called a scattering event. If enough of these scattering events occur, the photon completely loses its energy and is absorbed. If a photon is scattered such that it is re-emitted from the skin, it is reflected.

Photons with longer wavelengths (in the red region of the spectrum) are scattered less than photons with shorter wavelengths (in the blue region of the spectrum). This phenomenon is called wavelength-dependent scattering and explains why the skin appears red when you shine a bright light through it. It is also one of the reasons why the optical properties of the newborn's skin changes with advancing gestational and post-natal age. As the skin matures, it becomes thicker and there is greater keratinization of the cell membranes which increases the scattering of incident light.

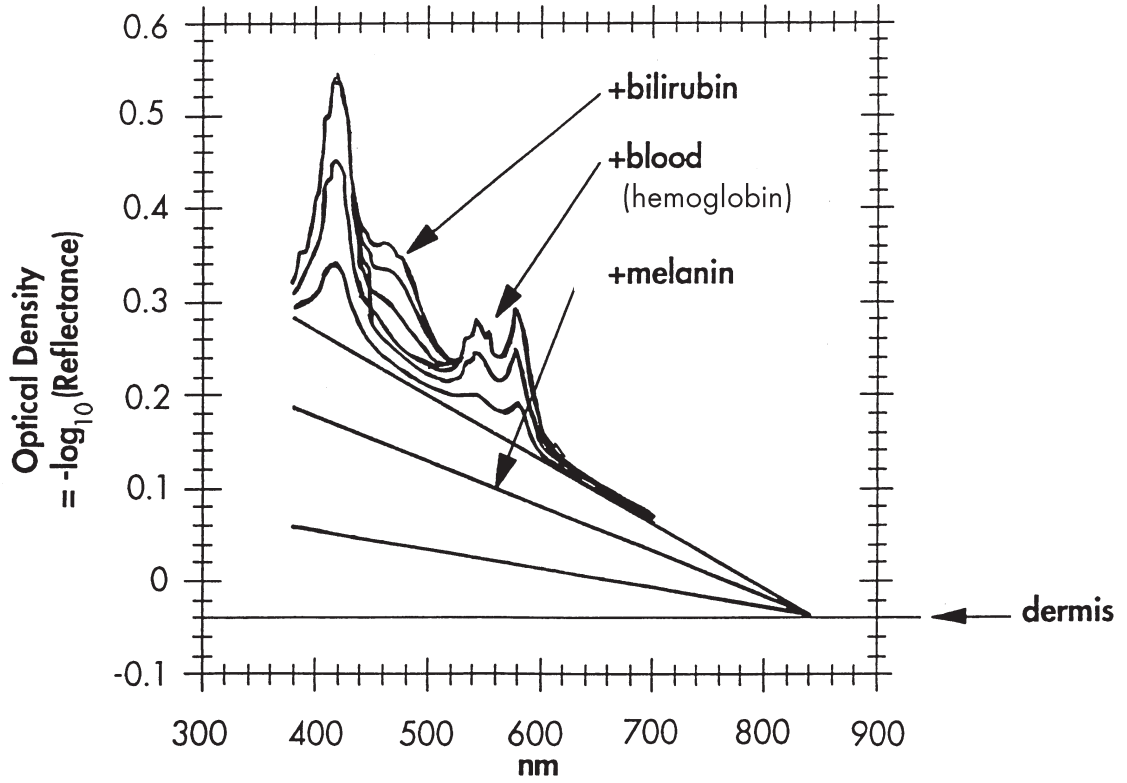
Photons of specific wavelengths are also preferentially absorbed by certain molecules. By plotting the absorption against the wavelength one can visualize characteristic absorption spectra of the particular molecules. For example, melanin has a near-linear absorption spectrum in the visible spectrum and, like the scattering phenomenon, there is greater absorption of photons with shorter wavelengths than in the red region of the spectrum. Conversely, hemoglobin is a much more complicated absorber which is compounded by the fact that oxyhemoglobin and deoxyhemoglobin have different profiles. The peak absorption of photons by bilirubin occurs at a wavelength of 460nm. This is in the blue portion of the spectrum and is the reason why blue lights are sometimes preferred for phototherapy. It is also in a region of the spectrum at which hemoglobin absorption is relatively low.

The light reflected from the skin of neonates and collected by the Bili*Chek* is analyzed with a highly sophisticated, proprietary algorithm to generate a serum bilirubin measurement. The major skin components (figure 1) which impact the spectral reflectance in newborns are (1) dermal maturity, (2) melanin, (3) hemoglobin, and (4) bilirubin. The intensity of the reflected light is converted to absorbance units, Optical Density (OD), for analysis. The total OD at each measured wavelength is equal to the sum of the component ODs. This is represented mathematically as:

$$OD_{total} = OD_{derm} + OD_{mel} + OD_{heme} + OD_{bili}$$

By utilizing known spectral characteristics of each component, the contribution to the total OD can be sequentially subtracted until bilirubin is all that is remaining.

Non-Invasive Skin Spectral Components[1]



[1] Jacques, S., Saidi, I., Ladner, A., and D. Oelberg. Developing an optical fiber reflectance spectrometer to monitor bilirubinemia in neonates.

Each of these components have also been considered in the development of the algorithm by which the Bili*Chek* computes the bilirubin measurement. By measuring the intensity of the reflected light at more than 100 individual wavelength bands across the visible spectrum, a spectral analysis can be performed. By normalizing against a reference standard, the Bili*Cal*™, the variations over time of the bulb and the photo-detectors are eliminated. The peak absorption of the bilirubin at approximately 460nm is measured by subtracting the absorption of the other components from the total skin absorption. This is represented by the equation below.

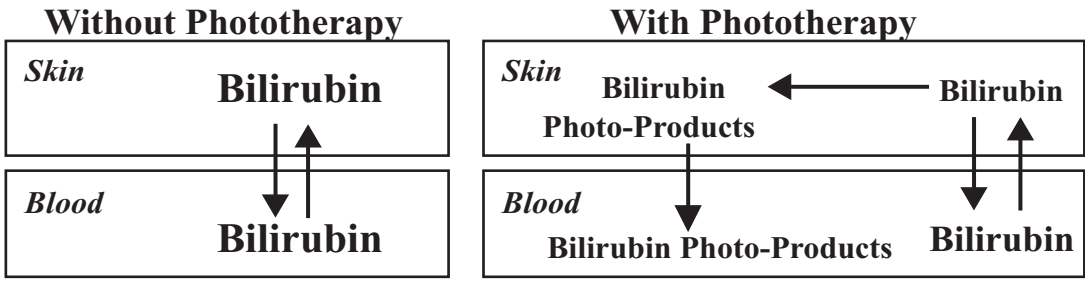
$$OD_{bili} = OD_{total} - OD_{mel} - OD_{heme} - OD_{derm}$$

The absorption of light by a molecule is proportional to its concentration. Therefore, the absorption of bilirubin, as calculated above, is proportional to the concentration of bilirubin in the subcutaneous capillary beds and subcutaneous tissue. By subtracting the contribution of the aforementioned components, the bilirubin absorbance can be quantified and is correlated to the laboratory total serum bilirubin levels.

[1] SPIE Proceedings 2975, *Laser-Tissue Interactions*, San Jose, CA Feb. 1997. 1-7.

Protecting a Measurement Site

Exposure of a neonate to phototherapy creates changes in the skin due to the therapuetic affects of phototherapy lights. If a small portion of the newborn skin is protected from the therapeutic affects of phototherapy lights, the relationship between the skin bilirubin in the protected skin site and blood bilirubin is likely to be maintained. The accuracy of the Bili*Chek*® transcutaneous bilirubin measurement taken from a protected site during and after phototherapy has been determined in a controlled clinical study. The recommendations in the User Instructions are based on the results of this study.



6.0 WARNINGS AND CAUTIONS

CAUTION: US federal law restricts this device to sale by or on the order of a physician.

WARNINGS

- The Bili*Chek*® Hand-Held Unit is to be operated only in conjunction with Respironics approved charger base, battery packs, power supply, and Bili*Cal*™ Individual Calibration Tips.
- Do not point at eyes while taking a measurement.
- Do not use on areas of the skin with visible bruising.
- If you suspect Bili*Chek* is interfering with other electronic devices or vice versa, try the following measures to correct it:
    - Relocate the device until the interference stops.
    - Move the Bili*Chek* farther away from the device.
    - Plug the Bili*Chek* Power Supply into a different power outlet so that the Bili*Chek* Power Supply and the device are on different breaker or fuse circuits.
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not puncture or incinerate the battery pack or dispose of in a landfill. Batteries should be disposed of properly according to local guidelines.
- Do not use outdoors or place in direct sunlight.
- The charger base unit (battery charger) should be plugged into a properly grounded outlet. Do not operate with damaged plug or cord.

CAUTIONS

- The Bili*Cal* Individual Calibration Tip should not be exposed to light for extended periods of time. Keep the Bili*Cal* in its package prior to use.
- If the product is dropped and frequent error messages occur, it should be inspected for proper operation by an authorized service representative.
- Do not immerse in water or other liquid.
- Do not let power cord hang over edge of counter or table as this may pose a tripping hazard.

CONTRAINDICATIONS

- The Bili*Chek* should not be used on patients who have undergone an exchange transfusion.
- Avoid using measurement sites with the following conditions since they can produce erroneous results:
    - Brusing
    - Birthmarks
    - Hematomas
    - Excessive Hairiness

NOTES

Certain medical conditions and medications are known to disrupt bilirubin-albumin carrying capacity and binding. These factors may alter the transcutaneous bilirubin measurement by increasing or decreasing the bilirubin deposition in the skin especially at high total serum bilirubin concentrations (>15 mg/dL or 255 µmol/L). Therefore, additional caution should be used in interpreting the Bili*Chek* measurement in patients with serious illnesses or complications such as septicemia, PDA, IVH, and RDS. In these patients, a separate serum bilirubin measurement should be considered if the Bili*Chek* indicates elevated bilirubin levels.

There is limited data on use of the Bili*Chek* on patients under intensive phototherapy (>30 µW/cm^2/nm or 1.5 m Wcm^2), double-sided phototherapy, or after exchange transfusions. Caution should be used in interpreting Bili*Chek* results under these conditions.

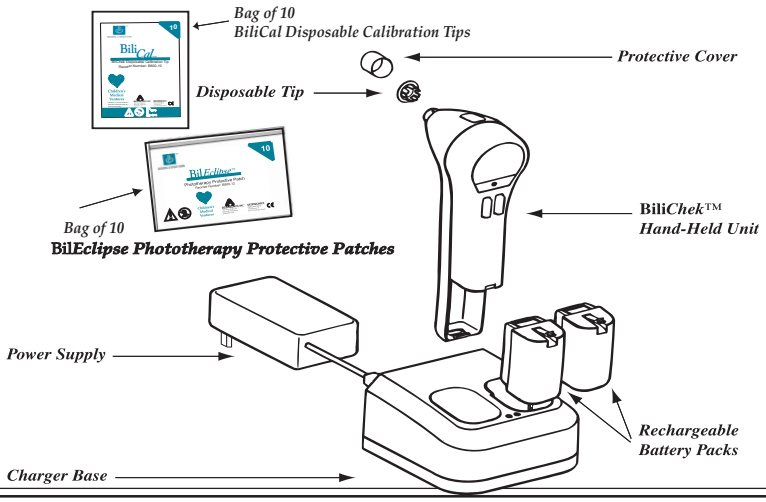
7.0 DESCRIPTION OF THE Bili*Chek*® System

The Bili*Chek* System consists of a hand-held unit called the Bili*Chek* (REF B800-13). The Bili*Chek* System (Part # B800/B801) also includes the following items:

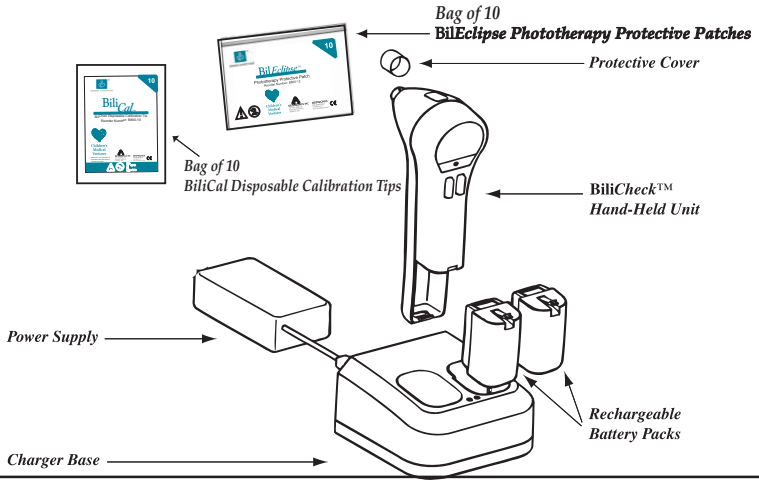
Quantity	Description	REF Number
2	Battery Packs	B800-20
1	Charger Base	B800-21
1	Bili*Chek* Power Supply - North America	B800-16
or		
1	Bili*Chek* Power Supply - International	B800-17
1	Bag of 10 Bil*Eclipse*™ Phototherapy Protective Patches	B800-12
1	Bag of 10 Bili*Cal*™ Disposable Calibration Tips	B800-10
1	User Instruction Manual - North America	B800-19
or		
1	User Instruction Manual - International	B800-23/B800-24
Optional	Table Top Power Supply (100V/250V) 47/63 Hz	B800-18

WARNING: The Bili*Chek* Hand-Held Unit is to be used only with these and approved replacement parts and accessories.

The Bili*Chek* System - North America



The Bili*Chek* System - International



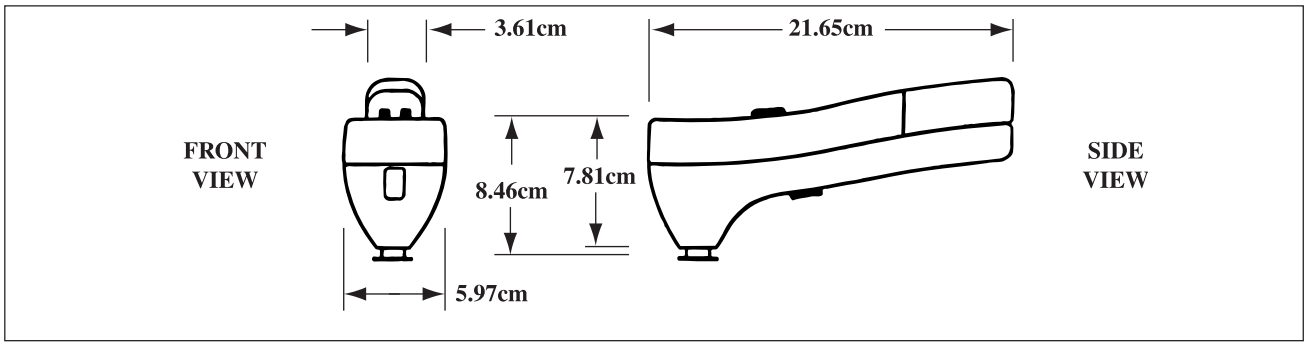
8.0 SPECIFICATIONS

Bili*Chek*® System

- Total weight ..... 974 g

Bili*Chek* Hand-Held Unit

- Weight (with battery pack) ..... 346 g
- Dimensions ..... Refer to figure below



Battery Packs

- Type ..... Ni-Cd
- Dimensions
  - Height ..... 6.5 cm
  - Depth ..... 4.8 cm
  - Width ..... 3.5 cm
  - Weight ..... 147 g
- Voltage 6V
- Capacity ..... 700 mA Hrs
- Measurements per full charge ..... Minimum 100 measurements on a single charge
- Life span ..... Minimum 1 year
- Recharge cycle ..... 4.6 hours maximum
- Discharge and recharge cycle ..... 9.2 hours maximum

Charger Base

- Dimensions
  - Height ..... 7.6 cm
  - Depth ..... 12.1 cm
  - Width ..... 12.4 cm
- Weight ..... 264 g

Light Bulb

- Type ..... Tungsten
- Bulb life ..... Minimum 30,000 measurements

Power Supply

- Input ..... 100-250 V, 47-63 Hz
- Output ..... 12 VDC, 2.75 Amp

Environmental Conditions for Use

Bili*Chek* System and Bili*Cal*™ Individual Calibration Tip may be stored at -40°C to 60°C (-40°F to 140°F) with noncondensing relative humidity of 95% for a duration of at least 24 hours.

Bili*Chek* System and Bili*Cal* Individual Calibration Tip are intended to operate between temperatures of 5°C to 40°C (41°F to 104°F) with 0% to 85% relative humidity without condensation.

9.0 FUNCTIONAL COMPONENTS

9.1 Bili*Chek*® Hand-Held Unit (HHU)

The Bili*Chek* Hand-Held Unit consists of the following functional components**:**

1. TRIGGER button -- The single button on the bottom of the unit is called the **TRIGGER**. It is used to initiate calibration and patient measurement.

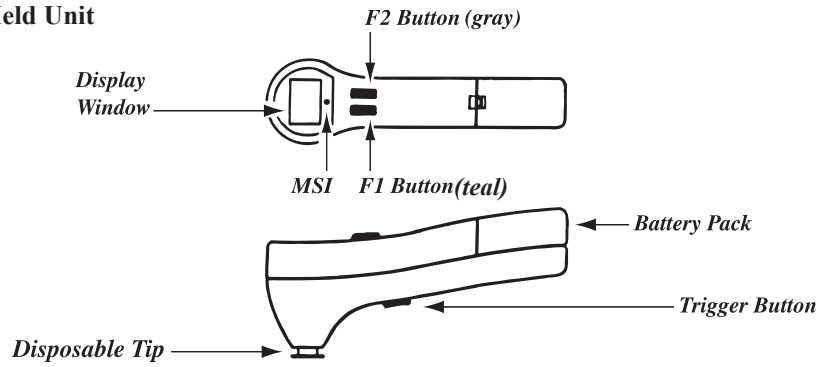
2. FUNCTION buttons -- The two buttons on the top side are FUNCTION buttons. The teal button on the left is referred to as **F1**, and the gray button on the right as **F2**. These are used to initiate non-routine functions such as set-up, changing time and date etc.

3. Bili*Cal* Individual Calibration Tip -- This tip serves five purposes:
   a) device calibration before each patient measurement,
   b) protection of the fiber-optic probe,
   c) protection of the surface of the calibration material,
   d) positioning aid to ensure proper placement of the probe,
   e) a clean surface for each patient measurement.

4 Display window -- The display window shows the bilirubin measurement, time and date, audio and battery icons, Measurement Status Indicator (MSI) as well as other system and error messages.

5. Battery pack -- Located in the bottom portion of the handle, it provides the electrical energy to operate the various components.

Bili*Chek* Hand-Held Unit



9.2 Charger Base

The charger base contains two wells, A and B, which recharge the battery pack in the Bili*Chek*® and a spare battery pack, respectively. The two small lights on the front of the charger base (Battery Status Indicators or BSI) indicate the operation of the battery charger and battery charge status.

THE CHARGER BASE

- The Bili*Chek* is placed in the left hand well "A" with the display window facing the operator.
- The spare battery pack is placed in the right hand well "B" with the latch up and facing the operator.

CAUTION: The Bili*Chek* unit will not fit in well "B" of the charger base. The battery pack can fit into well "A", but may not make correct connection to the charger base.

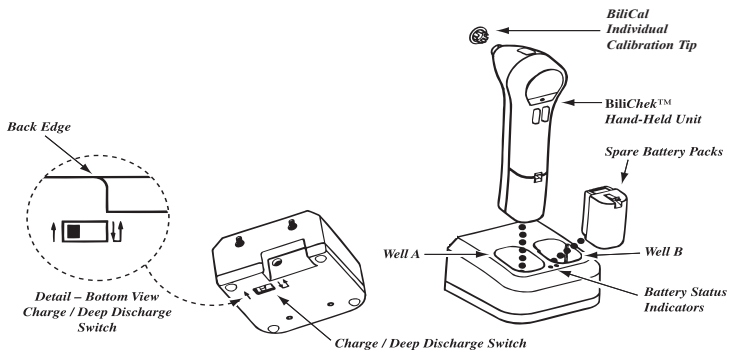
- In order to maintain optimal battery performance and battery life, the battery packs should periodically be fully drained of power. The charger base has the ability to manually drain the battery by using the "Charge/Deep Discharge" switch located on the bottom of the charger base. It is recommended by the manufacturer to discharge each battery pack every month. To drain a battery pack of power, place the Deep Discharge switch in the "right" (↓↑) position and place the Bili*Chek* battery pack in well B of the charger base. The discharge/recharge cycle will take approximately 4.6 to 9.2 hours depending on the amount of charge in the battery pack. The green light will illuminate when the battery pack has completely discharged and recharged. After both battery packs have been discharged and recharged, place the Deep Discharge switch in the "left" position (↑).

NOTE: Only the battery pack in Well B will be deep discharged and recharged.

CAUTION: Leaving the Deep Discharge switch in the "right" position at all times will drain the battery pack before every recharge. This will increase the duration of the recharging cycle and may reduce the overall life of the battery packs.

NOTE: If a battery pack is moved or bumped during the deep discharge cycle this may cause the deep discharge cycle to begin again.

The Bili*Chek* System



THE BATTERY STATUS INDICATOR (BSI)

BSI Color	Battery Charger Mode	Solution
Off	Battery pack not sensed in well or charger base not connected to power supply.	Place battery pack in well and/or check all power connections.
Green	Battery pack fully charged.	Battery pack ready for use.
Amber	Battery pack in well is charging, but not ready.	Continue charging until green light appears.
Amber flashing	Battery pack in well B is deep discharging.	Continue charging until green light appears.
Red flashing	Bad battery pack or charger base.	Replace battery pack in charger base. If problem persists with new battery pack, charger base has malfunctioned. Call for service.

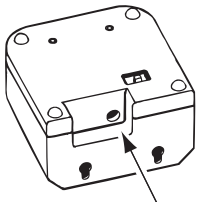
NOTE: When Deep Discharging the battery pack, the BSI will blink amber then become a constant amber color when charging.

NOTE: If the BSI is flashing red when battery pack is in place, try resetting the battery pack in the charging well. If problem persists, set a new battery pack in charger base. If problem continues with a new battery pack, the charger base has malfunctioned.

10.0 INITIAL SET-UP

- Visually inspect that all components are without physical damage. If damage is noted, please contact your local dealer/distributor or Respironics.
- Plug the power cord into the power supply and then into a grounded outlet.
- Connect the power supply to the charger base by inserting the plug into the socket on the rear of the charger base. The Battery Status Indicator (BSI) lights will flash red, green, amber, and then off (approximately 1 second each) to indicate proper operation.

Charger Base



REAR VIEW

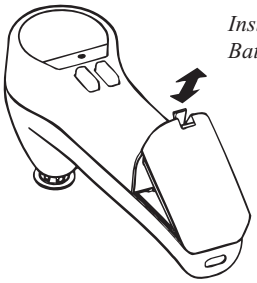
Connect Power Supply to Charger Base Socket

INSERTION AND REMOVAL OF BATTERY PACKS

- To install the battery pack, insert the bottom of the battery pack into the bottom of the Bili*Chek*® then rotate battery and snap into place.

- To remove the battery pack press the release latch at the top of the battery pack and rotate out of the Bili*Chek*.

Bili*Chek* Hand-Held Unit



Install and Remove Battery Pack

Before initial use, both battery packs should be fully charged. After installing one of the battery packs into the Bili*Chek,* insert the Bili*Chek* into the charger base well "A" as shown in section 10.2 of this manual. The indicator light will glow amber to indicate that the battery pack is being charged (consult the troubleshooting section of this manual if the indicator light is flashing red or is not illuminated). Now insert the auxiliary battery pack into well "B" as shown in section 10.2 of this manual. The BSI will glow amber to indicate that it is charging. Charge battery packs fully until green light is displayed on the BSI (refer to section 10.2 of this manual).

WARNING: The battery pack is designed to work only with the Bili*Chek*. Do not attempt to use the battery pack with other products.

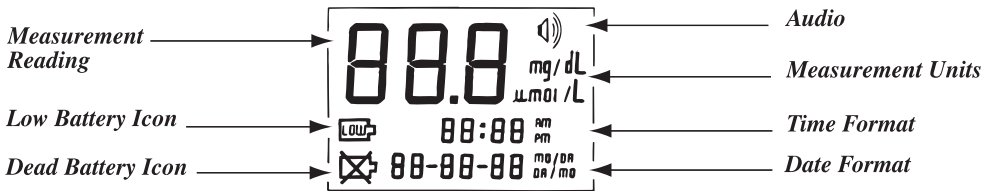
WARNING: Do not puncture or incinerate the battery or dispose of in a landfill. The battery pack should be disposed of properly according to local guidelines.

11.0 SET-UP MODE

Before you use the Bili*Chek*® for the first time, you must review or change certain factory settings. You can also use these procedures to change any of the settings at a later time. The following is a list of features that can be customized to your specific institution:

- Audio On/Off
- Measurement Units (mg/dL or µmol/L)
- Automatic Power Off Time Interval (60 or 120 seconds)
- Time Format (12H or 24H)
- Time
- Date format (MO/DA or DA/MO)
- Date

Bili*Chek* Display Window

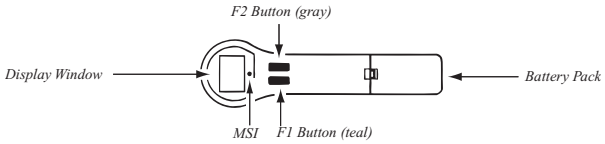


TO TURN THE UNIT ON

- Install a charged battery pack into the battery compartment. Ensure the battery pack is all the way in and securely latched.
- Press and release either **F1** or **F2.**
- The unit will perform a self test, momentarily displaying all LCD indicators, Measurement Status Indicator, software revision, current configuration screen and end at the home screen displaying the last measurement, time and date, or error code message (consult troubleshooting section of this manual if error code E00 is displayed).

NOTE: The Bili*Chek* Hand-Held Unit does not have an off switch. The Bili*Chek* will automatically turn off if it is idle for a specified period of time.

Bili*Chek* Hand-Held Unit



TO ACCESS THE USER SET-UP FUNCTION

- Press **F1** and **F2** at the same time, hold for one second, and then release. This places the unit in the Set-up Mode.
- While in this mode, the **F1** button (teal) advances to the next item. The **F2** key (gray) changes the value of the current item.

NOTE: To exit this mode at any time press and release F1 and F2 at the same time. All information that you have entered up to that point will be saved and displayed.

AUDIO ON/OFF

The audio Set-up, indicated by the speaker icon on the display, allows you to determine whether you want the system to provide sound (beeps) during operation.

NOTE: ON is the default setting.

- Press and release **F2** to toggle the speaker on and off.
- Press and release **F1** to accept your choice and advance to the next Set-up function.

SETTING THE MEASUREMENT UNITS

The system allows you to select the units in which the measurement will be displayed. The display will say SET and either mg/dL or µmol/L will be displayed.

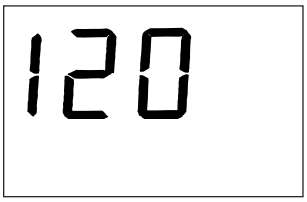
NOTE: The default value is mg/dL.

- Press and release **F2** to toggle between mg/dL and µmol/L.
- Press and release **F1** to accept your choice and advance to the next Set-up function.

AUTOMATIC POWER-OFF TIME INTERVAL

To conserve battery power, the unit has an automatic time-out feature. This means that the system will automatically turn off if it is idle for a specified period of time. Pressing **F1** or **F2** will restart the unit after it has powered off.

NOTE: The default is 120 seconds.



- Press and release **F2** to toggle between the options 60 and 120 seconds.
- Press and release **F1** to accept your choice and advance to the next Set-up function.

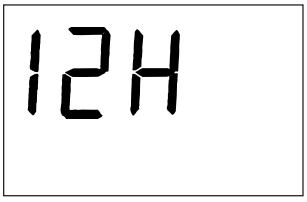
NOTE: This unit is equipped with a Critical Power-Off feature. After completing the calibration, the unit will sound an alarm if no measurement is performed within a set period of time. The unit will power-off 20 seconds later if F1 or F2 is not pressed. If the unit automatically shuts off, it is necessary to perform another calibration after restarting.

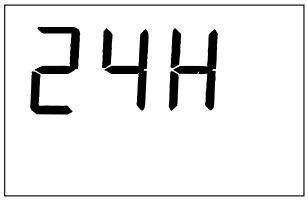
SELECTING THE TIME FORMAT

You can specify the time display format -- in the 12 hour clock format or the 24 hour clock format.

NOTE: The 12 hour format is the default setting.

- Press and release **F2** to toggle between 12H and 24H format.
- Press and release **F1** to accept your choice and advance to setting the time.



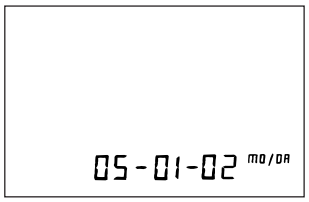


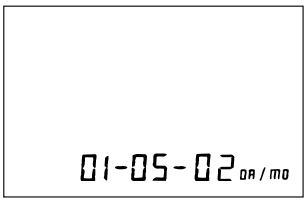
SETTING THE TIME

After choosing the time format, SET appears on the display and the current clock time will be shown.

- The hour digit will flash.
- Press and release **F2** to scroll through the hours.
- Press and release **F1** when the hour you want is displayed. The minute digits will now flash.
- Press and release **F1** to select what is displayed, or
- Press and release **F2** to scroll through the minutes.
- Press and release **F1** to accept your choice and advance to setting the date format.

SELECTING THE DATE FORMAT





You can choose to display the date in the month/day format or in day/month format.

NOTE: The month/day format is the default setting.

- Press and release **F2** to toggle between MO/DA and DA/MO format.
- Press and release **F1** to accept your choice and advance to setting the date.

SETTING THE DATE

Depending on the date format you selected, the current month or day will flash first.

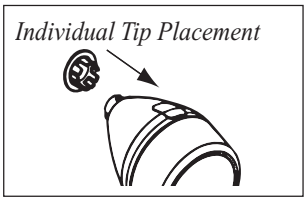
- The month (day) will flash.
- Press and release **F2** to scroll through the months (days).
- Press and release **F1** when the correct month (day) is displayed. The day (month) digit will now flash.
- Press and release **F1** to select the displayed value, or
- Press and release **F2** to scroll through the days (months).
- Press and release **F1** to accept your choice.
- Press and release **F1** to select the displayed year.
- Press and release **F2** scroll through the year.
- Press and release **F1** to accept your choice. The next digit will flash.
- Press and release **F1** to accept your choice.
- Continue this sequence until all digits have been entered.
- Press and release **F1** to accept your choice.
- Continue this sequence until all digits have been entered.

When you have accepted the desired date, your changes will automatically be saved and the unit will return to the home screen.

12.0 INSTRUCTIONS FOR USE

12.1 Completing a Patient Test -- Performing the Calibration

TO TURN THE UNIT ON

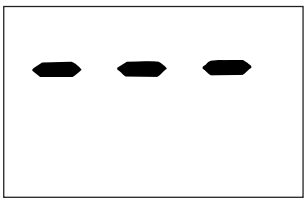


- If there is no battery pack, insert a charged battery pack into the battery compartment.
- Apply a new Bili*Cal*™ Individual Calibration Tip to the unit.
- Firmly press the Bili*Cal* Tip on to the Bili*Chek*® Hand-Held Unit to ensure proper seating of the Tip.
- Press and release either **F1** or **F2**.
- The unit will perform a self-test, momentarily displaying all LCD indicators, Measurement Status Indicator, software revision, configuration screen and end at the home screen.

NOTE: Press and hold F1 to illuminate the back light of the display window. This option is not available in the Set-up Mode.

NOTE: The home screen will remain until the TRIGGER button is pressed or the user Set-up Mode is entered.

CALIBRATION



- Press and release the **TRIGGER** button to start calibration.
- Three dashes (---) will flash in the display window and the MSI will be amber if a Bili*Cal* Tip is in place, indicating the system is ready to calibrate. If a Bili*Cal* Tip is not in place the MSI will be red. Attach a Bili*Cal* Tip before continuing.
- Press and release the **TRIGGER** button. The dashed lines will stop flashing indicating that the system is calibrating.
- When calibration is complete the MSI will be amber, you will hear a beep (if the audio is on), and the display window will read “005”.

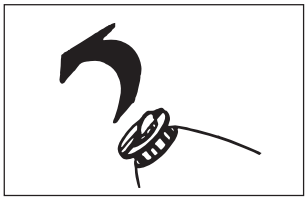
NOTE: If a problem occurs during calibration an error message will be displayed. Refer to the Troubleshooting Section of the manual for instruction.

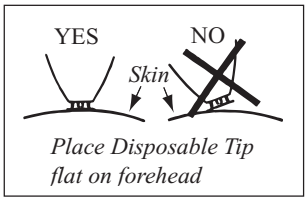
NOTE: To exit during calibration or measurement, press F1 and F2 to return to the home screen. The user will then need to repeat the procedure.

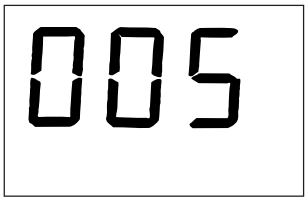
NOTE: This unit is equipped with a Critical Power-Off feature. After completing the calibration, the unit will sound an alarm if no measurement is performed within a preset period of time. The unit will power-off 20 seconds later if F1 or F2 is not pressed. If the unit automatically shuts off, it is necessary to perform another calibration after restarting.

12.2 Completing a Patient Test -- Performing the Patient Test

TAKING A MEASUREMENT







- After performing the calibration, pull on the Bili*Cal*™ tab and peel away the protective covering and calibration material from the Bili*Cal* Individual Calibration Tip and dispose. The display should be blinking "005" indicating that 5 measurements need to be made.
- Press and release the **TRIGGER** button. The unit is now activated and ready to take a measurement. Gently press the Bili*Cal* Tip against the infant's forehead. The Measurement Status Indicator (MSI) on the display will change from amber to green when proper pressure is applied. Do **not** continue to increase pressure, this will result in an E04 error message.
- The display will read "005" and will stop blinking when proper pressure has been applied. The measurement should take less than 2 seconds. At the end of the measurement, a beep will sound (if audio is on) and the display will change to "004".
- **Lift the Bili*Cal* Tip off the center of the infant's forehead between each measurement.** Press and release the trigger button before reapplying the Bili*Cal* Tip on the infant's forehead for each measurement. The current measurement being taken will be indicated on the display (005...003...001) and the unit will beep one time (if the audio is on) for each measurement successfully completed.
- Upon completion of the five measurements, a beep sounds (if the audio is on) and the test results are displayed with the current time and date.
- Remove and dispose of the Bili*Cal* Individual Calibration Tip.
- Place the Protective Cover onto the Bili*Chek* per manufacturer's recommendation. (If the protective cap is lost a Bili*Cal* may be used to protect the fiberoptic probe.)
- The Hand-Held Unit will turn off automatically.

TECHNIQUE TIP:

To assist the user with applying proper pressure while performing a patient measurement, a Measurement Status Indicator (MSI) has been included in the display. The following are the MSI color coding indicators:

- ***The MSI will be red until the user applies a BiliCal Individual Calibration Tip or during an error message.***
- ***The MSI is amber when the user performs a calibration.***
- ***The MSI is amber when the user begins a measurement.***
- ***The MSI turns green when proper pressure is applied during a patient measurement.***
- ***The MSI will return to amber if excessive pressure is applied.***
- ***If during a measurement the user moves out of the "pressure zone" the MSI turns red and an E04 error is displayed. Press and release F1 and F2 at the same time to retake the measurement. All previous successful measurements are saved.***

TECHNIQUE TIP:

Be sure to hold the BiliCal Individual Calibration Tip flat against the patient's forehead and in place until the test is complete. By visualizing the skin pressed flat all around the clear ring, the user can ensure the Disposable Tip is flat against the skin surface. Once proper pressure is applied, the display will stop blinking and the MSI will turn green. If the* Bili*Chek is moving during a measurement, the error code E04 is displayed.

NOTE: A single tone indicates a successful reading (if the audio is on). A double tone indicates that the reading was not successful, and an error code is displayed.

NOTE: If an error code is displayed, you do not need to calibrate the unit again. After an error is displayed, press and release F1 and F2 at the same time to return to the previous measurement screen. Reapply the tip to the baby's forehead and take another measurement.

WARNING: It is critical to calibrate the unit and apply a new Bili*Cal* Individual Calibration Tip immediately prior to performing a test. Inaccurate test results will occur if this is not done. Removal of the tip after calibration and prior to a patient measurement will result in loss of calibration. The entire calibration sequence must be repeated with a new Bili*Cal* Tip.

12.3 User Recommendations for Use During and After Phototherapy

During Phototherapy

- Select the site at which the Bili*Chek*® measurement will be taken. The preferred site is the flat area of the forehead between the infant's eyebrows.
- A photo-opaque[1] material (such as Bil*Eclipse*™ Phototherapy Protective Patch or adhesive skin patches) must be positioned over the measurement site on the forehead **prior to the start of phototherapy**. Any necessary precautions should be taken to ensure that the material does not move in such a way as to expose the measurement site to the phototherapy lights.
- All phototherapy lights should be turned off while a Bili*Chek* measurement is taken. Ensure that the preferred measurement site is still covered. Open the Bil*Eclipse* protective patch light blocking material and take the Bili*Chek* measurement from the preferred site. Close the Bil*Eclipse* flap and continue the phototherapy or remove the Bil*Eclipse* and discontinue the phototherapy as indicated. (You may choose to leave the Bil*Eclipse* in place after phototherapy is discontinued to identify the correct measurement site for future measurements.)

NOTE: Studies on the repeatability of the Bili*Chek* measurement have established precision specifications (see the Clinical Indications For Use for details). The source of variation in the measurement is the heterogeneous nature of skin and the bilirubin deposition. Small changes in successive transcutaneous bilirubin measurement of less than 2.0 mg/dL or 34 µmol/L (increases or decreases) should not be interpreted as definite trends.

Respironics recommends the use of the Bil*Eclipse* Phototherapy Protective Patch for all forms of phototherapy use. Some degree of light blocking can be provided with the other methods listed below.

Bil*Eclipse*

1. Always clean the skin site before you place the Bil*Eclipse* on the infant. Respironics makes no recommendations on the type of cleaning agent that is used. Any liquids, lotions, or creams will reduce the adhesiveness of the patch and increase the likelihood that it will fall off during phototherapy.
2. When you lift the LID of the patch to take a measurement, it may be helpful to place your finger on the edge of the BASE in order to make sure that the entire patch is not pulled off of the infant's skin.
3. When you close the LID, make sure that it is in good contact with the BASE around the entire patch. Although it is unlikely that light will penetrate the sides, any light that does reach the skin could affect the Bili*Chek* measurement.
4. After phototherapy has been completed, it is recommended that the Bil*Eclipse* be left on the skin until no future Bili*Chek* measurements are likely to be made. Although no further changes in the skin will occur after the phototherapy lights are turned off, leaving the patch in place will ensure that future measurements are made from the same, protected location.

Eye Patches:

Take precautions to ensure that the eye patches cover a large portion of the forehead, especially the site at which the Bili*Chek* measurement will be taken. Secure the eye patches to prevent them from moving and exposing the measurement site to the phototherapy lights.

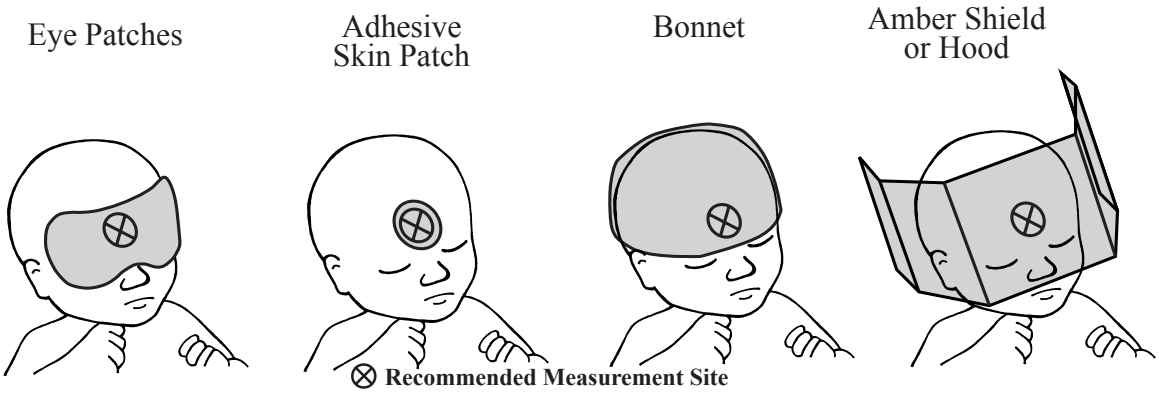
Adhesive Skin Patches:

Place the adhesive skin patch on the forehead at an anatomic site, such as between the infant's eyebrows, which can be identified even after the patch has been removed after phototherapy has been discontinued. Commonly available patches for skin temperature probes and monitor leads can be used for this purpose provided they are opaque to light. As an extra precaution, the patches can be left in place even after the phototherapy has been discontinued in order to identify the correct measurement site.

[1]Chin KC, MJ Moseley and SC Bayless "Light Transmission of Phototherapy Eyeshields," *Arch of Dis in Childhood,* 1987, 62(9), pp 970-1

Bonnets:
Although bonnets may cover the forehead during phototherapy it should be verified that they are opaque to light and extra precautions must be taken to prevent them from moving and thereby exposing the forehead to the phototherapy lights. Since many materials used for bonnets are not completely opaque, it is recommended that an adhesive patch be placed on the forehead under the bonnet.

Amber Shields and Hoods:
Amber phototherapy shields or hoods which are used to protect the newborn's eyes during phototherapy still allow some light to penetrate. Some manufacturer's test data indicates the light blocking cut-off is ~520 nm. Some clinical studies have indicated that green lights (with wavelengths greater than 520 nm) may have phototherapeutic effects. The Bili*Chek* transcutaneous bilirubin measurement has not been verified with the use of these products, therefore, it is recommended that an adhesive patch or other light blocking method should be used in conjunction with these products at this time.



After Phototherapy:
Appropriate measures should be taken to ensure that any measurements taken from newborns after they have received phototherapy are taken from a site on the forehead that was not exposed to the phototherapy lights. The exact procedures that should be used will depend on the type of phototherapy protection used as described above. Although leaving a Bil*Eclipse* Phototherapy Protective Patch in place is not necessary once the phototherapy lights are removed, it will ensure that the same site is used for subsequent Bili*Chek* measurements.

NOTE: Clinical studies indicate that as many as 48 hours may be required before the skin treated by phototherapy returns to the bilirubin level of an unexposed site.

NOTE: Newborns that are placed near windows with high exposure to sunlight may experience "natural phototherapy". This may be particularly true when the newborn has already been discharged home and is returning to a hospital, clinic, or office facility for testing.

13.0 TROUBLESHOOTING GUIDE

At times, you may receive an error code (E01, E02, etc.) or warning symbol in the display window. The following is a guide to help you correct a system problem.

Display Window	Indication	Solution
E00	No user set-up information identified.	Install a charged battery pack into the battery compartment. Press **F1** and **F2** at the same time, hold for one second and then release. This places the unit in the Set-up mode. Enter settings specific to your institution, see section 12.0 for Set-up mode instructions.
E01	Calibration measurement is unacceptable.	Press and release **F1** and **F2** at the same time. Ensure the Bili*Cal*™ Tip is in place. Press the **TRIGGER** button to restart calibration (---). If error continues try another Bili*Cal* Tip. If error persists, remove the Bili*Cal* and clean the optical measurement tip (under disposable tip) with approved cleaning agent, repeat calibration. If error continues replace measurement light bulb (see section 15.0 for replacement instructions) and repeat calibration. If error E01 persists, call for service.
E02	Patient measurement is unacceptable.	Press and release **F1** and **F2** at the same time. Retest the patient. If E02 occurs again, replace Bili*Cal*, repeat calibration and retest patient. If E02 continues, call for service.
E03	Disposable Tip removed between the calibration and measurement scan or the Bili*Chek* is being used in an environment with too much ambient light.	Press and release **F1** and **F2** at the same time. Remove the Bili*Cal*. Replace with a new tip and recalibrate. If E03 error is indicated even though the Disposable Tip has not been removed, the ambient light level is too high. The Bili*Chek* should not be used outdoors, too close to infra-red radiant warmers, or in areas with high levels of sunlight. Move to an area of lower light levels and press the **F1** and **F2** buttons at the same time.
E04	Too much movement during the measurement.	Press and release **F1** and **F2** and retest the patient.
E05 HIGH	Measurement is out of clinically proven range.	Obtain a Total Serum Bilirubin level (TSB).
E10	Light bulb is burned out.	Replace measurement light bulb, see section 15.0 for replacement instructions. If error continues, call for service.
E99	System error is detected.	Call for service.
	Low battery pack, there are approximately 10 measurements left when the icon first appears.	Replace current battery pack with a fully charged battery from the charger base and place discharged battery pack into well “B”for charging.
	Discharged battery pack, no measurements can be taken.	Replace current battery with a fully charged battery pack from the charger base and place discharged battery pack into well “B” for charging.

THE BATTERY STATUS INDICATOR (BSI)

BSI Color	Battery Charger Mode	Solution
Off	Battery pack not sensed in well or charger base not connected to power supply.	Place battery pack in well and/or check all power connections.
Green	Battery pack fully charged.	Battery pack is ready for use.
Amber	Battery pack in well charging, but not ready.	Continue charging until green light appears.
Amber flashing	Battery pack in well deep discharging.	Continue charging until green light appears.
Red flashing (battery pack in well)	Bad battery pack or charger base.	Replace battery pack. If problem persists with new battery pack, charger base has malfunctioned. Call for service.

Contact your local dealer or Respironics if frequent errors occur.

14.0 CLEANING AND MAINTENANCE

The Bili*Chek*® System is made of an easy to clean smooth surface. The following cleaning agents are recommended for use:

- KleenaSeptic®
- Cavicide®
- 70% - 90% Isopropyl Alcohol
- 1% Bleach

Spray cleaning agent of choice onto a damp cloth to wipe clean the Bili*Chek* System. This same procedure may also be used for the display window.

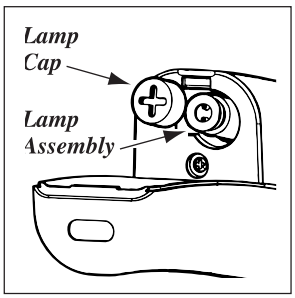
WARNING: Do not immerse in water or other liquid. If liquids spill onto unit, wipe with a damp cloth and let unit dry before using.

WARNING: Do not attempt to clean and/or reuse Bili*Cal*™ Individual Caibration Tip.

CAUTION: Clean the optical measurement tip (only) with 90% or higher Isopropyl Alcohol using a soft optical surface cleaning wipe.

CHANGING THE MEASUREMENT LIGHT BULB

If the light bulb is not operating and error code E01 or E10 (refer to troubleshooting section of this manual) is displayed, it is necessary to replace the light bulb using a manufactured approved Replacement Bulb Kit (REF B800-22).



- Remove the battery pack from the bottom of the Bili*Chek* unit.
- Remove the protective label.
- Remove the lamp cap using a flat tip or Phillips head screw driver.
- Grab the loop of the light bulb with forceps or similar tool/instrument.
- Gently pull to remove lamp assembly.
- Insert factory specified replacement lamp assembly.
- Install the replacement lamp cap supplied with the bulb, do not over tighten.
- Apply new protective label.
- Securely attach battery pack.
- Apply new Bili*Cal* Tip, supplied with replacement kit.
- Turn power on.
- Perform multiple calibrations until unit accepts calibration.

WARNING: The Bili*Chek* is to be used only with an approved Replacement Bulb Kit from the manufacturer. Do not over tighten lamp cap.

WARNING: There are no field serviceable components which can be accessed from the battery pack opening. Do not attempt to separate the upper and lower bodies or remove the junction screw. Doing so could damage the fiber-optics and will invalidate the manufacturers warranty.

15.0 ATTACHING THE CHARGER BASE TO A WALL

A charger base template has been provided below, to assist with mounting the charger base to the wall. The charger base, with the Bili*Chek*® unit, and additional battery pack weight is approximately 974 g.

For wall mounting of the charger base the user should purchase the appropriate anchor for the type of wall. For example, if the user is mounting to a sheetrock wall, hollow wall fasteners should be used. If the user is mounting to a wood wall, wood screws should be used.

Insert the screw into the wall leaving a gap of approximately .25 cm of the screw exposed between the wall and the head of the screw. Place the unit on the screw to check the fit and adjust as required.

WARNING: Do not mount charger base over or near any heating device, sink or basin. Do not hang anything or place any objects other than the Bili*Chek* Hand-Held Unit and/ or battery packs in the charger base. Maximum downward force on charger base should not exceed 2500 g.

Full Size Charger Base Template